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Using Big Data To Monitor Drug Safety

According to a new report by researchers at RTI Health Solutions (RTI-HS) and parent company RTI International, while healthcare databases allow greater access to real world medical data, using this data to evaluate the safety of medical products is complex and requires careful research consideration.

The report has been published in *Current Epidemiology Reports* and shows that if care was not taken, there was a real risk to patients and healthcare systems because of false safety signals and false safety assurances.

The RTI researchers found that several data sources did not include information on potential risk factors that could have an impact on health outcomes. These included the use of illicit substances and over-the-counter medicines, adherence to medication and smoking. In addition, it is difficult to study diseases such as cancer because the databases contain relatively short-term data.

"The monitoring of drug safety cannot yet be delegated to smart algorithms applied to healthcare databases," said Elizabeth Andrews, PhD, Vice President of Pharmacoepidemiology and Risk Management at RTI-HS and co-author of the paper. "With all the fervor around the potential for big data, it's critical to keep in mind the substantial differences across databases in content, coding systems and practices, duration of available medical history and follow-up time, quality of outcome information, and clinical practice patterns."

The report also included a review of insurance claims, electronic health records, and disease registries used for pharmacovigilance and drug safety, and explored the evolution of methods so as to provide quality to the research and offer the best practice recommendations.

According to Suzanne L. West, PhD, Fellow at RTI International and senior author of the paper, the objective of the research was to study the evolution of databases and the implications of using these data since using healthcare databases to evaluate medicines is becoming increasingly popular. The findings suggest that healthcare databases have indeed improved, allowing researchers to study products in diverse settings. However, caution should be exercised when using these data since healthcare databases contain real world evidence which is often not controlled or verified against source records.

"A drawback of clinical trials is that they are highly controlled and highly monitored to ensure strict adherence to protocol; however, that's not how people take drugs in the real world," said Andrea V. Margulis, MD, ScD, senior research epidemiologist and co-author of the paper. "Real world data have problems too because they are so uncontrolled. With this report, we wanted to explore the pros and cons of working with real world data."

Source: Newswise

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